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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/808,031	03/03/1997	SUMIKO INOUE	377.5888P	5819

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/16/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/808,031

Applicant(s)

INOUYE ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

The request filed on 8/28/2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/808,031 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants previous amendment of claim 17 is acknowledged. Claims 1-17 are still at issue and are present for examination.

Applicants' arguments filed on 7/2/2001, paper No. 37, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: On page 11, lines 17-22, the specification recites "Xiong and Eickbush (1990)", "Hsu et al. 1992b",

"Sun et al. 1991" and "Herzer et al. 1992", yet these references are not listed with the other references in the specification so it is unclear as to the exact citation upon which applicants are referring.

Appropriate correction is required.

Claim Objections

Claim 7 is objected to because of the following informalities: Claim 7 is dependent on rejected claim 6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9, 10, 11, 12, 13-16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 9-11 are directed to all possible isolated and purified bacterial reverse transcriptases isolated from a bacterium which is capable of synthesizing an msDNA as determined by the reverse transcriptase extension in vitro screening test (claims 9 and 11), wherein said bacterium is selected from the group of genera consisting of *Myxococcus*, *Escherichia*, *Proteus*, *Klebsiella*, *Flexabacter*, *Cytophaga*, *Stigmatella*,

Salmonella, *Nannocystis*, *Rhizobium* and *Bradyrhizobium* (claim 10). Claims 13 and 14 are directed to all possible isolated and purified bacterial reverse transcriptases (claim 14), wherein said bacterial reverse transcriptase synthesizes msDNA and are essential for the synthesis of msDNA in vivo (claim 13). Claims 1-6, 15, 16 are directed to all of the above possible bacterial reverse transcriptases wherein said reverse transcriptase contain the four amino acid motif, SEQ ID NO: 50 (claims 1, 5, 6, 15, 16), a second four amino acid motif, SEQ ID NO: 51 (claim 2), a third three amino acid motif, Asn-Xaa-Xaa₁ (claim 3), and a fourth four amino acid motif, SEQ ID NO: 52 (claim 4) and the above reverse transcriptase in which the motifs SEQ ID NO: 51, Asn-Xaa-Xaa₁, SEQ ID NO: 50 and SEQ ID NO: 52 are arranged in order starting from the amino terminal end of the RT (claim 12). Claim 17 is also drawn to all possible bacterial reverse transcriptase in which the motifs, Asn-Xaa-Xaa₁, SEQ ID NO: 51, SEQ ID NO: 50 and SEQ ID NO: 52 are arranged in order starting from the amino terminal end of the RT. The specification, however, only provides the seven representative species shown in Figure 14, encompassed by these claims. There is no disclosure of any structure for the RTs of claims 9-11, 13 and 14 and claims 1-6, 12, 15, 16 and 17 provide a limited structure to function/activity relationship of the disclosed RT species such that a skilled artisan would not recognize applicants were in possession of the claimed genus.

Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim 12 is further under this rejected under 35 U.S.C. 112, first paragraph, because a claim to a bacterial reverse transcriptase in which the motifs SEQ ID NO: 51, Asn-Xaa-Xaa₁, SEQ ID NO: 50 and SEQ ID NO: 52 are arranged in order starting from the amino terminal end of the RT is not supported by the original specification, specifically figure 14, and is thus considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite and confusing in that it claims a bacterial reverse transcriptase in which the motifs SEQ ID NO: 51, Asn-Xaa-Xaa₁, SEQ ID NO: 50 and SEQ ID NO: 52 are arranged in order starting from the amino terminal end of the RT. As discussed above, no such bacterial reverse transcriptases are described in the specification and the reverse transcriptases described in figure 14 each contain the motifs SEQ ID NO: 51, Asn-Xaa-Xaa₁, SEQ ID NO: 50 and SEQ ID NO: 52 in a different order than that recited in claim 12, thus it is confusing as to which bacterial reverse transcriptases are being claimed in claim 12.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8, 9-11, 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lim and Mass (Cell 56:891-904, 1989).

Lim and Mass teach the reverse transcriptase –dependent synthesis of a covalently linked, branched DNA-RNA compound in *E. coli*. Lim and Mass teach the cloning of a 3.5 kb chromosomal segment of *E. coli* B which contains the coding regions for the DNA component, the RNA component and an open reading frame encoding a reverse transcriptase, which is required for the formation of the DNA-RNA compound in vivo and in vitro. Lim and Mass further teach the transformation of *E. coli* JM103 with the construct pT-14 (See figure 12, page 897) and the isolation of a Mono Q Eluate fraction comprising the encoded bacterial reverse transcriptase as determined by the synthesis of msDNA (See figure 16, page 900). This fraction which comprises the bacterial reverse transcriptase encoded by the pT-14 DNA construct, anticipates the above rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Inouye et al. (US Pat. 5,320,958 or US Pat. 5,434,070), in view of the combination of Rice et al. (July 1993), Xiong et al. (1990) and Hsu et al. (Apr. 1992).

The rejection is stated in the previous office actions, paper Nos: 24, 36 and 38, and applicants present arguments in paper Nos: 26 and 37.

As stated in the previous advisory, paper No: 38, 7/25/2001, applicants traverse the current 103 rejection of claims 1-17 on the following basis. Applicants submit that the instant application is a continuation of U.S. Patent Application Serial No. 08/269,118 filed June 30, 1994, thus U.S. Patent 5,434,070 issued July 18, 1995 is not prior art against this application. Applicants further submit a declaration that the invention disclosed and claimed in the present application was conceived prior to June 14, 1993, the issue date of U.S. Patent 5,320,958 and applicants claim priority from the applications which issued as the '070 and '958 patents. This argument is not found persuasive for the following reasons. In the original 103 rejection of these claims it was noted by the examiner that the instant application receives the benefit of the filing date only of June 30, 1994, for subject matter of RT's from any organism other than *E.coli* and *M. xanthus*. Applicants are reminded that it is not the issue date of the above U.S. Patents that is important, when swearing behind said patents, but rather the filing date, which precedes the priority date for the instant application, as well as the date of the

submitted 1.131 declaration. Further applicants are reminded that a properly executed 1.131 declaration must be signed by all inventors/applicants.

Claims 1-6, 8, 9-11, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu et al. (Journal of Bacteriology 174(7): 2384-2387, April 1992), as applied to claims 1, 2, 5, 6, 8, 9-11, 13-16 above, and further in view of Lim and Mass (Cell 56:891-904, 1989).

Hsu et al. teach the similarity between the *Myxococcus xanthus* and *Stigmatella aurantiaca* reverse transcriptase genes associated with multicopy, single-stranded DNA. Hsu et al. present the nucleotide sequence of the encoding gene and the amino acid sequence of the *Stigmatella aurantiaca* reverse transcriptase enzyme.

As discussed above, Lim and Mass teach the reverse transcriptase -dependent synthesis of a covalently linked, branched DNA-RNA compound in *E. coli*. including the transformation of *E. coli* JM103 with the construct pT-14 and the isolation of a Mono Q Eluate fraction comprising the encoded bacterial reverse transcriptase as determined by the synthesis of msDNA

One of ordinary skill in the art would have been motivated to express this nucleic acid sequence to confirm Hsu et al's. hypothesis that the nucleic acid encodes a protein with reverse transcriptase activity. The reasonable expectation of success comes from the high degree of knowledge in the art with respect to the expression of recombinant proteins as is demonstrated by Lim and Mass (Cell 56:891-904, 1989).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
November 14, 2001


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